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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/214,848	01/14/1999	TERUAKI SEKINE	1208/P502PCT	8123

7590 07/27/2004
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WASHINGTON, DC 20006

EXAMINER

CHOI, FRANK I

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/214,848

Applicant(s)

SEKINE, TERUAKI

Examiner

Frank I Choi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-27,29 and 31-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-27,29 and 31-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1616

DETAILED ACTION

Examiner withdraws the finality of the prior Office Action to apply new grounds of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12-27, 29, 31-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ochoa et al. (U.S. Pat. 5,443,983) in view of Rosenberg (US Pat. 4,690,915) and Melder et al. for the reasons of record set forth in the prior Office Actions in further view of the acknowledged prior art and Wallace et al. or the acknowledged prior art and Rooney et al., each in further view of Babbitt et al. (US Pat. 5,766,920) and Ochoa et al. (US Pat. 5,296,353) and the further reasons below.

Ochoa et al. (U.S. Pat. 5,443,983), Rosenberg (US Pat. 4,690,915, and Melder et al. were discussed in the prior Office Action and the same are incorporated herein.

Applicant acknowledges that T-cells are involved in cellular immunity against cancer and viruses (Specification, Pgs. 1, 2). Further, it is acknowledged that lymphocytes, including T-cells and NK cells, can be activated and stimulated by IL-2 and that lymphocytes can be activated and stimulated with IL-2, with or without CD3 antibodies, including against viruses, such as, EBV and CMV (Specification, pgs. 3,4).

Art Unit: 1616

Wallace et al. or Rooney et al. teach that T-cells activated with IL-2 are effective against EBV (See entire disclosure of each).

Babbitt et al. teach activation of autologous T-lymphocytes with OKT3 and cytokines, including IL-2, for treatment of viruses, such as herpesvirus, such as herpes simplex virus and cytomegalovirus, and Epstein Barr virus (See entire document, especially, Column 2, lines 22-68, Column 3, Column 7, lines 40-49, Column 20, lines 53-68, Column 21, lines 1-16).

Ochoa et al. (US Pat. 5,296,353) teach activation of autologous T-lymphocytes with anti-CD3, such as OKT3, and cytokines, including IL-2, for treatment of cytomegalovirus and Epstein Barr virus (See entire document, especially, Column 3, lines 32-50, Column 7, lines 54-68, Column 8, lines 1-35, Column 11, lines 29-54, Column 12, lines 15-54)

Applicant's arguments have been duly considered but they are deemed unpersuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 231 USPQ 375 (Fed. Cir. 1986). Further, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 208 USPQ 871 (CCPA 1981).

Contrary to Applicant's arguments, the prior art above indicates that one of ordinary skill in the art would expect that treatment for cancer would be suggestive of treatment for herpes virus. Applicant argues that NK lymphocyte cells and LAK cells are different from T-lymphocytes. However, only claims 35,36 and 37 recite T-lymphocytes. In any case, the

Art Unit: 1616

teachings of Babbitt et al. and Ochoa et al. (US Pat. 5,296,353) disclose the use of autologous T-lymphocytes against viruses of the herpesvirus group.

Likewise, in view of the teachings of Babbitt et al. and Ochoa et al. (US Pat. 5,296,353), Applicant's arguments relative to Rooney and Wallace as being donor lymphocytes does not overcome the rejection. Further, with respect to the compositions claims and process of making claims, the term "autologous" relates to intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Since the term "autologous" relates to administration to the person from which the lymphocytes were obtained, Applicant has made no showing that the T-cell lymphocytes in Wallace or Rooney could not be administered to the persons' from which the lymphocytes were obtained.

As indicated in the prior Office Actions, in view of the teachings of Babbitt et al. and Ochoa et al. (US Pat. 5,296,353) and the fact that Applicant's claims are not directed to treatment of HIV infections or the use of IL-2 alone, Applicant's citation to the Nature Medicine article which discusses the failure of treatment of HIV infection in a single patient, which the authors' theorized could be for any of a number of reasons for reasons, in which IL-2 only activated lymphocytes were used, is not sufficient to overcome the combined teachings of the prior art above.

Art Unit: 1616

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

FIC

July 13, 2004



SABIHA QAZI, PH.D
PRIMARY EXAMINER